



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,115	01/07/2004	Timothy D. Hey	DAS-104XC1	8974
23557 7590 12/19/2006 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER KOSSON, ROSANNE	
			ART UNIT	PAPER NUMBER
			1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TH

Office Action Summary	Application No. 10/754,115	Applicant(s) HEY ET AL.	
	Examiner Rosanne Kosson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7,12,14,21-25,30,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7,12,14,21-25,30,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2006 has been entered.

Claims 1, 7, 12, 14 and 21-24 have been amended. Claims 3, 6, 8-11, 13, 15, 15, 26-29 and 31 have been canceled. Claims 32-33 have been added. Accordingly, claims 1, 2, 4, 5, 7, 12, 14, 21-25, 30, 32 and 33 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In view of Applicants' amendment to claim 12, the objection is withdrawn.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1, 2, 4, 5, 12 and 14 are again rejected, and claims 32-33 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims recite that the insecticide of the claimed method includes forms of Proteins A, B and/or C that are any

Art Unit: 1652

fragments (each of these proteins may be truncated at any position or positions) having at least 47% (claim 32) or at least 95% (claim 33) sequence identity to SEQ ID NO: 34, 56% sequence identity to SEQ ID NO: 45 or 50% sequence identity to SEQ ID NO: 47, or any variants in which any number of amino acids at any positions may be substituted by conservative amino acid changes. No such variants or truncation fragments are disclosed in the specification. This rejection was discussed in the previous Office actions.

Applicants have traversed the rejection, asserting that paragraph 21 of the specification discusses protease processing of the A proteins and that Examples 16 and 27 of US 6,528,484 also show that protease-activated A proteins retain insecticidal activity. Applicants also assert that various sections of the specification disclose the production and use of the claimed fragments.

In reply, Applicants have not stated which sections of the specification disclose making and using fragments of the claimed proteins, SEQ ID NOS: 34, 45 and 47, and no such sections can be found. Paragraph 21 discusses screening genomic libraries to find certain *Photorhabdus luminescens* genes. The genes for the claimed proteins are not mentioned specifically, and no fragments of any genes are discussed. As for US 6,528,484, Example 16 discusses cleavage of the Tcb A protein by an endogenous protease to form one activated fragment, but Tcb A is not a claimed protein. Example 27 discusses cloning the tcd A gene into *E. coli*. No protein fragments are disclosed here. As for variants, Applicants assert that a wide variety of B and C proteins can potentiate protein A, and Applicants have recited several B and C proteins that potentiate the elected protein A. But, Applicants have not explained how these other B and C proteins are sequence variants of the elected sequences. Applicants have not explained which parts of the elected sequences must be conserved and which may be varied and the extent to which (by amino acid position and specific amino acid substitution) the

Art Unit: 1652

variable positions may be varied, with very concrete information, so that one of skill in the art would know which specific individual variant sequences have the same activity with respect to SEQ ID NO: 34 as SEQ ID NOS: 45 and 47. Applicants have also not explained which variants of SEQ ID NO: 45 retain the activity that this sequence has with the pair SEQ ID NO: 34-SEQ ID NO: 47 and which variants of SEQ ID NO: 47 retain the activity that this sequence has with the pair SEQ ID NO: 34-SEQ ID NO: 45.

In view of the foregoing, the rejection of record is maintained.

Claims 21-24 and 30 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims recite that the insecticide of the claimed method includes forms of Proteins A, B and C that have a size within a particular range and that are encoded by any polynucleotide that maintains hybridization for any length of time under medium stringency conditions (0.1X SSC, 0.1% SDS and 55° C) with the polynucleotide encoding Proteins A, B and C. No such hybridization-maintaining polynucleotides are disclosed in the specification. Thus, one of skill in the art would have no idea which proteins and polynucleotides Applicants have in mind that they wish to include within the scope of the claimed invention. Also, one of skill in the art would have no idea which polynucleotides that maintain hybridization under the claimed conditions encode proteins that have the claimed activities, either as an insecticide or as a potentiator of an insecticide. This rejection was discussed in the previous Office action.

Applicants assert that 0.1X SSC and 55° C are highly stringent conditions that are more

Art Unit: 1652

highly stringent than those in the Written Description guidelines. Applicants also assert that they need not disclose any washing conditions, because those may be determined by one of skill in the art.

In reply, the claims do not recite "highly stringent conditions." As previously discussed, the claims recite a moderately stringent temperature for the hybridization reaction, and because no polynucleotides are disclosed that hybridize to the polynucleotides encoding the claimed proteins under any conditions, the sets of polynucleotides obtained by hybridization under the claimed conditions and those obtained by hybridization under stringent conditions cannot be compared. Also, because the claims do not recite any washing conditions, the washing conditions include those of low stringency, and thus encompass polynucleotides that would not bind to polynucleotides encoding the claimed proteins at the end of a high-stringency treatment experiment. Many polynucleotides that hybridize under a particular set of conditions are removed by washing under high stringency conditions. The rejection is not that one of skill in the art would not be able to determine high-stringency washing conditions, conditions needed to obtain polynucleotides encoding proteins that have the desired properties. The rejection is that Applicants have not disclosed any species of the claimed genus of polynucleotides that hybridize to the polynucleotides encoding SEQ ID NOS: 34, 45 and 47 under Applicants' "stringent conditions." In view of the foregoing, the rejection of record is maintained.

Claims 1, 2, 4, 5, 12, 14, 21-24 and 30 are again rejected, and claims 32-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising SEQ ID NO: 34, SEQ ID NO: 45 and SEQ ID NO: 47, does not reasonably provide enablement for a method of controlling or inhibiting an insect by contacting the insect with a

Art Unit: 1652

composition comprising any truncation fragment or any conservatively substituted variant of any or all of SEQ ID NO: 34, SEQ ID NO: 45 or SEQ ID NO: 47. The specification also does not provide enablement for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising proteins encoded by polynucleotides that hybridize under stringent conditions to the polynucleotides encoding SEQ ID NOS: 34, 45 and 47. Further, the specification does not provide enablement for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising proteins that have 47% or 95% sequence identity to SEQ ID NO: 34, 56% sequence identity to SEQ ID NO: 45 and 50% sequence identity to SEQ ID NO: 47. Even with the functional limitation that the highly variant and truncated sequences have the same insecticidal or potentiating activities, no such sequences are disclosed in the specification. Consequently, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection was discussed in the previous Office action.

Applicants have not responded specifically to the enablement rejection. They state merely that their response to the written description rejection also addresses the enablement rejection.

In reply, the response to the written description rejection does not address the enablement rejection. Applicants have claimed several genera of proteins and polynucleotides encoding these proteins (variants, fragments, sequences that hybridize under medium-stringency conditions and sequences having 47% or 95%, 56% and 50% sequence identity to the elected proteins A, B and C, respectively), but have not disclosed any species of these genera. Because Applicants have not disclosed any species of these claimed genera, and because Applicants have not provided any systematic procedure for identifying these

Art Unit: 1652

undisclosed species, it cannot be predicted that such species exist. Additionally, it would be undue experimentation to come up with the systematic guidance needed to identify and test these species. In view of the foregoing, the rejection of record is maintained.

Claim Rejections - 35 USC § 112, second paragraph

Claims 12, 14 and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the term "maintains hybridization." Applicants claim a method of using proteins encoded by polynucleotides that maintain hybridization under the stringency conditions of 0.1XSSC and 55° C (medium stringency). It is not clear for how long the hybridizing polynucleotides maintain their hybridization- a fraction of a second, hours, days, etc. It cannot be determined if Applicants mean to claim polynucleotides that remain hybridized during the hybridization and washing steps or polynucleotides that remain hybridized during the hybridization steps only (a larger group). As a result, the metes and bounds of the claims are unclear. Appropriate correction is required. Applicants may add a definite time value or definite steps of the hybridization experiments during which the hybridizing polynucleotides do hybridize. Or, Applicants may use a different term that is definite.

This rejection was discussed in the previous Office action, and Applicants have not responded to it, apart from asserting that selecting an appropriate number of washes and length of washing time is within the capability of one of skill in the art.

In reply, the rejection is not that one of skill in the art would not know how to prepare a washing buffer or determine the washing parameters that he needs. The rejection is that it cannot be determined what spectrum of polynucleotides Applicants mean to claim, because the claims recite only medium stringency hybridization conditions and no washing conditions. The

Art Unit: 1652

meaning of the claims with respect to the recited polynucleotides is unclear and requires further clarification. In view of the foregoing, the rejection of record is maintained.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 depends from canceled claim 8. Thus, the metes and bounds of the claim are unclear, as it cannot be determined which claim Applicants mean to have claim 14 depend from. Appropriate correction is required. The claim dependency must be corrected.

Claim Rejections - 35 USC § 103

Upon reconsideration of Applicants' arguments and the prior art, this rejection is withdrawn.

Double Patenting- Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 7, 12, 14, 21-25, 30, 32 and 33 are provisionally rejected on the ground

Art Unit: 1652

of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 28 and 29 of copending Application No. 11/070,573. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a method of controlling or inhibiting an insect, comprising contacting the insect with a composition comprising Proteins A, B and C (SEQ ID NOS: 34, 45 and 47, respectively), while the copending claims recite a method of preventing an insect from feeding on a plant, a more specific form of inhibition, comprising contacting the insect with a composition comprising Proteins A, B and C (SEQ ID NOS: 23, 6 and 14, respectively, which are the same sequences as instant SEQ ID NOS: 34, 45 and 47). In the copending application, Proteins B and C are part of a fusion protein, while, in the instant application, Proteins B and C may or may not be linked in a fusion protein, but the copending claims are a narrower version of the instant claims. These two claim sets would not have been restricted apart had they been presented together in one application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 7 and 25 are objected to as being dependent upon a rejected base claim (claims 1 and 21, respectively), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Art Unit: 1652

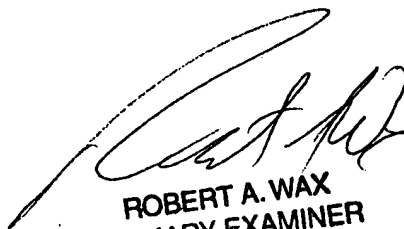
supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

2006-12-05

Rosanne Kosson


ROBERT A. WAX
PRIMARY EXAMINER